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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,139	01/28/2004	Stefan Schreck	ECV-5541DIVCON	1979

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EDWARDS LIFESCIENCES CORPORATION  
LEGAL DEPARTMENT  
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IRVINE, CA 92614

EXAMINER
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MILLER, CHERYL L

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 10/766,139	Applicant(s) SCHRECK, STEFAN	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 18,19,21,22,24-26,38,39 and 43-57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18,19,21,22,24-26,38,39,43-57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 27, 2006 has been entered.

### ***Response to Arguments***

Applicant's arguments with respect to claims 18-22, 24-26, and 38-49 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 101***

Claims 18, 25, 26, 38, 39, 43-45, 47-51, and 54 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The applicant has claimed in claim 18 a "tissue-engaging base portion", which positively recites a portion of the body (tissue, or the base *engaging* tissue). Portions of the body are considered non-statutory subject matter. It is suggested to change the above to recite --tissue-engagable base portion-- or --a base portion *adapted to engage tissue*--.

Similar problems occur in claims 25, 26, 38, 39, 43-45, 47-51, and 54 wherein "Tissue-engaging base" is recited.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38, 39, and 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 38, line 5 recites, "having an outflow end". However it is unclear as to what this limitation is referring to. Exactly what has an outflow end has not been defined, thus this limitation is indefinite.

Further, claim 38 lines 6-8 claim the base to have/comprise posts extending from the outflow end. This is indefinite. If indeed the outflow end is the actual "end" of the base, it is unclear how posts may extend from the end and still be considered part of the base. It would seem that since the posts extend away from the base, they could not be considered part of the base, but another component extending away from the base. Claims 39 and 43 depend upon claim 38 and inherit all problems associated with the claim. (It is noted to the applicant, that claim 54 similarly claims posts, but in a much more definite way. That is the *valve further comprises* posts, instead of the *base having* posts, see claim 54 for a more definite recitation).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 50-53, 55, and 56 are rejected under 35 U.S.C. 102(e) as being anticipated by Cribier (US 6,908,481 B2, cited previously). Referring to claim 50, Cribier discloses a two part prosthetic heart valve (see figs.14-15 and respective portions of the specification) comprising a tissue-engaging base (10) that is expandable, and a leaflet subassembly (10') including a support structure (stent frame 11 of 10') and three valve leaflets (see valve 14 with three leaflets shown in detail in fig.4b, located between struts 17) attached to the support at commissures (along line 20, seen in detail in fig.7; or at 19 in fig.6b), and further a plurality of discrete connectors (barbs and openings) on the leaflet subassembly (hooks) and the tissue-engaging base (openings in stent frame 10 for hooks to engage; col.20, lines 33-38) configured to join upon axial movement and expansion (see figs.15a-h).

Referring to claims 51-53, 55, and 56, Cribier discloses the base to be plastically expandable (col.9, lines 14-22; see fig.15a, 15b). Cribier discloses the support (stent frame 10') comprising a wireform (wire struts 11; seen in figs.14, 15) having alternating cusps and commissures (the zigzag sinusoidal wire mesh having peaks and troughs, which are considered by the examiner to be the "cusps" and "commissures"). Cribier discloses the wireform peaks and troughs to have connectors (hooks; col.20, lines 33-38). The connectors are joined by axial compression, see fig.15c-15f, wherein the subassembly is moving axially and radially to connect (snap in, upon expansion) to the base.

Claims 44-48, 50-53 and 55-57 are rejected under 35 U.S.C. 102(e) as being anticipated by Garrison et al. (US 6,425,916, cited previously). Referring to claim 44, Garrison discloses a two part prosthetic heart valve (see figs.8-10) comprising an expandable tissue-engaging base

(8), a leaflet subassembly (6, 6C) comprising a support (26) and three heart valve leaflets (38; see fig.11, 34, 38) attached at commissures (commissures considered to be a joining place or line; or near 32 in figs.8-10), and a plurality of discrete mating connectors (protrusions 34 and openings 14 seen in figs.9; col.5, lines 29-35, OR barbs 100 and openings 14, see fig.29, 30; col.9, lines 64-67; col.10, lines 1, 16-24) on the leaflet subassembly (openings 14) and the tissue-engaging base (100 OR 34) adapted to mechanically couple together at the time of the implant procedure. Applicant has claimed the positioning of the leaflets with respect to the base “after assembly” when they are “adapted to mechanically couple”. However, because the claim refers or *positively claims the subcombination of two separate parts* (thus the intermediate product), the actual final product, “after assembly” is not positively claimed thus Garrison’s two parts need only be capable of such positioning. Garrison’s two parts are capable of being located in such relative positioning. That is, Garrison’s connector on the subassembly (100 or 34) are adapted to connect into any opening 14 on the base (8), thus capable of the leaflets being positioned outside the tubular body. Garrison has even shown the capability of being able to place the two parts at different positions relative one another, see figs.20, 27, 28, see col.10, lines 26-36. It is inherent that Garrisons subassembly connectors (100 or 34) are capable of being placed in the top outflow end openings 14, such that the leaflets are not located within the tubular body.

Referring to claims 45-48, Garrison discloses a plastically-expandable base (8), see figs.3-4, col.2, lines 1-5, and an elastic wireform (26) subassembly (6) having cusps and commissures (see fig.10, 30). Garrison discloses the subassembly to mechanically couple to the base at a plurality of locations (all along the circumference, where each barb 100 or protrusion 34 is located is a different location; see figs.9, 30). Garrison discloses the base (8) to have

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mechanical coupling members (openings 14) and the subassembly (6) to have couple members (100 or 34).

Referring to claim 50, Garrison discloses a two part heart valve comprising an expandable base (8), a leaflet subassembly (6) including a support (stent 26) and three leaflets (38) attached at commissures (see fig.10), and a plurality of discrete mating connectors on each the base and subassembly (the base 8 has opening 14 in which protrusions 100 or 34 of the subassembly 6 engage; col.9, lines 64-67; col.10, lines 1, 16-24).

Referring to claims 51-53 and 55-57, Garrison discloses a plastically expandable base (8; col.2, lines 1-5; figs.3, 4), a subassembly comprising a wireform having cusps and commissures (peaks and valleys of stent 26; see fig.10), mating connectors (100) on the subassembly (6) located on the cusps and commissures (see figs.29, 30) and are joined to the base by axial compression, snap fit (will snap into openings 14 upon expansion after axially positioning). Garrison discloses one of the mating connectors (openings 14) to comprise a partial circle opening (seen in figs.8, 9, portions of openings 14 form a partial circle).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18, 19, 21, 22, and 24-26 are rejected under U.S.C. 103(a) as being unpatentable over Cribier (US 6,908,481 B2, cited previously) in view of Garrison et al. (US 6,425,916 B1,

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cited previously). Referring to claims 18 and 26, Cribier discloses a two part prosthetic heart valve (see figs.14-15 and respective portions of the specification) comprising a substantially cylindrical tissue-engaging base (10) that is expandable (see figs.15a-15h) and a leaflet subassembly (10') including a metallic support structure (stent frame 11 of 10') and three valve leaflets (see three leaflets shown in detail in fig.4b) attached to the support at commissures (along line 20, seen in detail in fig.7 or at 19 in fig.6b), the support having a fabric covering (19), the leaflets attached to the support (stent 11) by stitches along the fabric covering (along line 20, see fig.6, 7), the leaflet subassembly being a separate component and configured to mechanically connect to the base (fig.15) at the time of the procedure. Cribier discloses the two-part valve substantially as claimed, however discloses the valve subassembly and base to be a plastically expandable material instead of a self-expanding material as claimed. Garrison teaches in the same field of two part valves, the use of both plastically expandable AND self-expandable subassemblies and bases, the self-expanding subassemblies/bases being an obvious alternative to plastically expandable since no additional expansion mechanisms are required in the delivery system (col.8, lines 10-23), making delivery more simplistic. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Cribier's two part valve with plastically expandable subassembly/base, with Garrison's teaching of using self-expanding subassemblies/bases in the alternative to plastically expandable subassemblies/bases for two part valves, in order to provide a system that is more simplistic, requiring less delivery parts (expansion mechanism).

Referring to claims 19, 21, 22, and 24-25, Cribier discloses leaflets that are bioprosthetic tissue (col.15, lines 6-9) and wherein the base is plastically expandable (col.9, lines



14-22) and the subassembly comprises a wireform having cusps and commissures (struts 11 make up wire mesh stent having peaks and valleys which are considered the cusps and commissures, seen in fig. 14, 15). The heart valves are shown to be attached to the wireform (see figs).

#### *Allowable Subject Matter*

Claims 38, 39, and 43 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

Claims 49 and 54 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 101, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

#### *Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

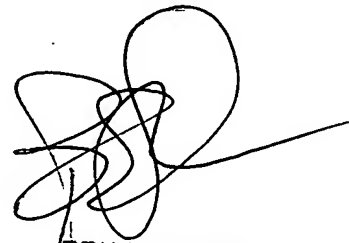
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cheryl Miller



**BRUCE SNOW**  
**PRIMARY EXAMINER**